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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,639	03/16/2001	Sumio Kawano	KNI-147-A	7389

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EXAMINER

VALENTIN, JUAN D

ART UNIT	PAPER NUMBER
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2877

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,639

Applicant(s)

KAWANO, SUMIO

Examiner

Juan D Valentin II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 8.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-7 and 9-13 rejected under 35 U.S.C. 102(b) as being fully anticipated by Soller et al. (USPN '119, hereinafter Soller).

Claim 1

Soller discloses an analytical method of analyzing blood using near infrared spectroscopy comprising the steps of applying light through a blood collection receptacle to a sample of the blood contained in the receptacle (col. 2, lines 8-12). Soller further discloses detecting at least one of diffusely reflected light, diffusely transmitted light, and diffusely transmitted and reflected light from the blood sample in the blood collection receptacle by an optical sensor to measure a near infrared absorption spectrum of the blood sample (col. 2, lines 31-44). Soller further discloses modifying the measured spectrum using a calibration equation which has been determined in advance (col. 6, lines 58-67 & 41-50) from a spectrum measured using a receptacle with the same specifications as the said blood collection receptacle and following the steps above relative to blood specimen with known object characteristics, thereby determining an object characteristic of the blood sample (col. 10, lines 18-38).

Claim 2

Soller further discloses an analytical method wherein the wavelength of near infrared light applied to the blood in the blood collection receptacle is 700nm - 1100nm (col. 11, lines 51-55).

Claim 3

Soller further discloses an analytical method of analyzing blood wherein the calibration equation is determined using a chemometrics technique selected from the group consisting of multiple linear regression (MLR), principal component regression (PCR) and PLS regression (col. 8, lines 33-38).

Claim 4

Soller discloses an analytical apparatus for analyzing blood comprising a block provided with a housing portion for a translucent blood collection receptacle (col. 20, line 6). A near infrared apparatus provided with a spectroscope for dispersing near infrared light from a light source or from a sample of blood contained in the blood collection receptacle and an optical sensor for detecting the near infrared light (col. 2, lines 31-44). A light conduction means for conducting the near infrared light emitted from the light source or the spectroscope to the blood collection receptacle within the housing portion and for conducting, directly or through the spectroscope, at least one of diffusely reflected light, diffusely transmitted light, and diffusely transmitted and reflected light from the blood sample within the blood collection receptacle to the optical sensor (col. 19, lines 34-44). A control means for outputting a measured spectrum of the blood sample to the near infrared apparatus and for modifying the measured spectrum using a calibration equation that has been determined in advance (col. 6, lines 58-67 & 41-50) from a spectrum measured using the apparatus, a receptacle with the same specifications as the said

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blood collection receptacle and blood specimens with known object characteristics, for thereby computing an object characteristic of the blood sample (col. 19 and 20, lines 42-58 and 10-17, respectively).

It is inherent that the calibration equation determined in advance would be determined using a receptacle with the same specifications as the blood collection receptacle used to determine the object characteristics of the sample being analyzed in order to insure standardization and consistency in measurement results of the unknown sample.

Claim 5

Soller discloses an analytical apparatus for analyzing blood wherein a white light source (col. 19, lines 40-41) is used as the light source, and a diode array (col. 19, line 43) is used as the optical sensor. It is inherent that a tungsten lamp is a white light source, therefore it is the position of the Office that the reference of Soller reads upon the applicants claimed limitations.

Claim 6

It is the inherent and well known in the art to use silicon detectors with monochromatic light during spectroscopy analysis. It is the position of the Office that even though Soller does not disclose the use of monochromatic light source in conjunction with a silicon detector directly, it is inherent in the art of spectroscopic analysis of a sample to use a silicon detector or equivalent when undertaking spectroscopic analysis of a sample with a monochromatic light source. In light of the applicants disclosure, there is no critically distinguishing light source or detector feature in the applicants disclosure that exemplifies novelty over prior art disclosure. Therefore, applicant will be appreciated that the reference of Soller reads on applicants claimed limitation.

Claim 7

Soller discloses an analytical apparatus for analyzing blood wherein the light conduction means comprises an optical fiber (col. 12, lines 59-62).

Claim 9

Soller discloses an analytical apparatus for analyzing blood wherein the calibration equation is determined in advance using the near infrared apparatus in relation to a plurality of blood specimens with different, known object characteristics (col. 10, lines 18-38).

Claim 10

Soller discloses an analytical apparatus for analyzing blood wherein the blood collection receptacle is a tube or bag (col. 6 & 19, lines 8-10 & 57-58, respectively).

Claim 11

Soller discloses an analytical apparatus for analyzing blood wherein the light conduction means comprises an optical fiber bundle (col. 12, lines 59-62).

Claim 13

Soller discloses an analytical apparatus for analyzing blood wherein the blood collection receptacle is a tube or bag (col. 6, lines 8-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Soller in view of Brown et al. (USPN '678, hereinafter Brown).

Claim 8

Soller substantially teaches the claimed invention except that it fails to show a block provided with a temperature control means for stabilizing the blood sample within the blood collection receptacle at a predetermined temperature. Brown shows that it is known to provide a temperature regulator (col. 8, lines 16-25) for a automatic blood analysis apparatus. It would have been obvious to someone of ordinary skill in the art to combine the device of Soller with the temperature regulator of Brown for the purposes of providing a means for regulating the temperature of a sample being analyzed.

3. Claim 14-16, 19, & 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Soller in view of Kuenstner (USPN '448).

Claim 14

Soller substantially teaches the claimed invention except that it fails to show wherein multiple different object characteristics of said blood sample are determined. Kuenster shows that it is known to provide multiple different object characteristics of said blood sample (col. 1, lines 13-18) for analyte determination by infrared spectroscopy. It would have been obvious to someone of ordinary skill in the art to combine the device of Soller with the multiple different object characteristics of Kuenster for the purposes of providing a method of clinical analyte determination using infrared spectroscopy (col. 4, lines 25-27).

Claims 15 & 19

Soller substantially teaches the claimed invention except that it fails to show wherein multiple different object characteristics of said blood sample include chemical components and/or physiochemical characteristics. Kuenster shows that it is known to provide multiple different object characteristics of said blood sample including chemical components and/or physiochemical characteristics (col. 1, lines 13-18) for analyte determination by infrared spectroscopy. It would have been obvious to someone of ordinary skill in the art to combine the device of Soller with the multiple different object characteristics of Kuenster for the purposes of providing a method of clinical analyte determination using infrared spectroscopy (col. 4, lines 25-27).

Claims 16 & 20

It is obvious and well known to someone of ordinary skill in the art to analyze blood samples to determine object characteristics including red blood cells, hematocrit, hemoglobin, total protein total cholesterol, and sugar (glucose). Applicant will be appreciated that the reference of Soller in view of Kuenster reads on the claimed limitations.

4. Claim 14-16, 19, & 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Soller in view of Ikeda et al. (USPN '674, hereinafter Ikeda).

Claims 17 & 21

Soller substantially teaches the claimed invention except that it fails to show wherein an optical path length for said blood sample receptacle is 1-2 cm. Ikeda shows that it is known to provide an optical path length for a blood sample receptacle is 1-2 cm (col. 6, lines 37-58) for an

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apparatus for determining functions of blood cells. It would have been obvious to someone of ordinary skill in the art to combine the device of Soller with the optical path length of Ikeda for the purposes of providing a suitable means for the measurement of fine variations in platelets in blood cells (col. 4, lines 12-15).

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Response to Arguments

6. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., receptacle

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according to the invention may be an ordinary tube or bag and an optical path length of 1-2 cm) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. Applicant's arguments with respect to claim 8 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juan D Valentin II whose telephone number is (703) 605-4226.

The examiner can normally be reached on M-Th., Every other Fr..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank Font can be reached on (703) 308-4881. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9318 for regular communications and (703) 872-9319 for After Final communications.

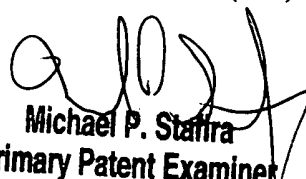
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308- 0955.



Juan D Valentin II
Examiner 2877

JDV

July 11, 2003



Michael P. Staffra
Primary Patent Examiner
Technology Center 2800